UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

December 08, 2016

MEMORANDUM

Subject: Efficacy Review for Opti-Cide Max; EPA File No. 70144-L; DP Barcode: D433951

From: Ibrahim Laniyan, Ph.D.
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Applicant: Micro-Scientific, LLC.
755 Tri-State Parkway
Gurnee, IL 60031

Formulation from the Label:

Active Ingredients	% by wt.
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride	0.425 %
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chloride	0.425 %
Ethanol	7.750 %
Isopropyl alcohol	12.250 %
Other Ingredients:	79.150 %
Total	100.000 %

I. BACKGROUND

The product, Opti-Cide Max (EPA File No. 70144-L), is a new product. The applicant requested to register the product as a disinfectant (bactericide, fungicide, tuberculocide, virucide) for use on hard, non-porous surfaces in household, commercial, institutional, food processing, food service, animal care, and hospital or medical environments. The product is for use on pre-cleaned surfaces. Studies were conducted at MICROBIOTEST, located at 105 Carpenter Drive in Sterling, VA 20164.

This data package, identified as D433951, contained a letter from the applicant's representative to EPA (dated April 29, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4(Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), twenty-nine studies (MRID 499075-09 through 499075-37), Statements of No Data Confidentiality Claims for all studies, and the proposed label (dated 04/29/16).

Note: During product development, Weiman Products, LLC (EPA Company Number 1130) purchased Micro-Scientific, LLC (EPA Company Number 70144). As such, data volumes list "*Weiman 1 Minute Germicidal Solution*" as the tested material. After purchasing Micro-Scientific, LLC, Weiman Products, LLC chose to market the proposed product under the Micro-Scientific, LLC product brand which is reflected on the administrative materials and product label. There have been no changes made to the product in the conversion from the "*Weiman 1 Minute Germicidal Solution*" product name to the "*Opti-Cide MAX*" product name.

II. USE DIRECTIONS

The product is designed for disinfecting surfaces. The product may be used to treat hard, non-porous surfaces, including: air vents, aquariums, armrests, ATM buttons, bar tops, bath tubs, bedrails, benches, biohazard team equipment, biological monitoring devices, bowls, bridles, brushes, cabinets, cages, call buttons, carts, cash registers, chainsaw blades, changing tables, clipper blades, clippers, coin dispensers, combs, computer keyboards, computer screens, cots, counters, CPR training devices, CPR training manikins, curing lights, cuspidors, cutting boards, decks, dental equipment (as specified on the proposed label), diaper changing tables, diaper pails, dictating machines, diving equipment and masks, door handles, doorknobs, drinking fountains, dry suits, dumbbells, elevator buttons, elevator panels, empty whirlpool tanks, escalator handrails, face shields, faucets, fish tank equipment (as specified on the proposed label), fixtures, floors, flower pots, foot spa bowls, furniture (as specified on the proposed label), gaming machines, garbage cans, garbage compactors, garden equipment, goggles, grass mower blades, grooming tables, gym mats, handcuffs, handrails, harnesses, hospital and medical equipment (as identified on the proposed label), kennels, leashes, light lens covers, light pull switches, lights, litter boxes, lockers, manicure implements, masks, mats, microscopes, monitors, optical wear (excluding contact lenses), pedicure equipment, play-care equipment, razors, remote controls, reptile habitats, scales, scissors, seats, shower doors, showers, sinks, slot machines, soap containers, soap dishes, stands, stools, tables, tanning beds, telephones, toilets, tools, toys, trash cans, tree saws, walls, weight machines, wet suits, and window sills. The product may be used to treat soft surfaces, including: cloth furniture, coated mattresses, coated pillows, curtains, leather surfaces, mattress covers, and upholstered fixtures. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: coated surfaces, glass, laminated surfaces, metal (e.g., aluminum, brass, stainless steel), painted surfaces, plastic (e.g., acrylic,

polycarbonate, polypropylene, polystyrene, polyvinylchloride, vinyl), and Plexiglas. Directions on the proposed label provide the following information regarding use of the product:

> As a disinfectant: Apply the product to pre-cleaned surfaces. Allow to remain wet for 30 seconds, 1 or 2 minutes (as appropriate). Wipe dry using a clean paper or cloth towel; or rinse surfaces using potable water and either wipe surfaces dry or allow to air dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different product lots at the LCL, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers]. To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required in AOAC Germicidal Spray Products Test to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Performance requirements when using AOAC Use-Dilution Method are killing in 57 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538 and 54 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Each microbe should be tested three times. Each test should be conducted against a separate batch of product for a total of three batches. Each of the three tests should be conducted on a different day.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots at the LCL. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^5 microorganisms survived the carrier-drying step.

Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity Test Method or the AOAC Germicidal Spray Products Test Method): Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Products may be tested using one of four recommended methods: the AOAC Tuberculocidal Test Method, Tuberculocidal Activity of Disinfectants Test Method with significant modification of the standard test conditions of contact time and/or temperature, Quantitative Tuberculocidal Activity Test Method, and AOAC Germicidal Spray Products Test Method.

When using the existing or modified AOAC Tuberculocidal Activity Test Methods, or the AOAC Germicidal Spray Products Test Method, ten (10) carriers for each of two samples,

representing two different batches of product at the LCL, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). When using the existing or modified AOAC Tuberculocidal Activity Test Method, or the AOAC Germicidal Spray Products Test Method, killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of two additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. Three surfaces for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples at LCL representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 499075-09 "AOAC Germicidal Spray Test Supplemental Against Methicillin-Resistant *Staphylococcus aureus* (ATCC 33592)" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-165.

This study was conducted against Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.1.11.12.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until drenched. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the

carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin-resistant Staphylococcus aureus (ATCC 33592) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Methicillin-resistant Staphylococcus aureus (ATCC 33592) to oxacillin. See table 4, page 10 of the laboratory report.

2. MRID 499075-10 "AOAC Germicidal Spray Test Supplemental Against Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625)" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-180.

This study was conducted against Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625). Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.1a.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36-37°C at 42-44% humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625) to oxacillin. See table 4, page 10 of the laboratory report.

3. MRID 499075-11 "Virucidal Hard-Surface Efficacy Test - Feline Calicivirus (Surrogate for Human Norovirus)" for Weiman 1 Minute Germicidal Solution, by Semhar Fanuel. Study conducted at MICROBIOTEST. Study completion date – 11/11/15, 2010. Laboratory Project Identification Number 474-150.

This study was conducted against Feline Calicivirus (FCV), Strain: F9 (ATCC VR-782), using CrFK Cells, ATCC CCL-94) as the host system. Two lots (12735 and 22735) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol

No. 474.1b.09.02.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 21°C and 35.4 - 37.9% RH. Two replicates were tested. For the single product lot, separate dried virus films were sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface and held for 58 seconds at 20-21°C. Following exposure, the plates were neutralized with RPMI 1640 with 10% Newborn Calf Serum (NCS), 0.5% Polysorbate 80, and 0.5% Lecithin, and 0.01 N HCI. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were 10-fold serially diluted and assayed. CrFK cells in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated 7-9 days at 36±2°C in 5±1% CO_2. Following incubation, the infectious virus was scored microscopically for cytopathic effects and cytotoxicity. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

4. MRID 499075-12 "AOAC Germicidal Spray Test Healthcare" against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442); for Weiman 1 Minute Germicidal Solution; by Kelsey Roach. Study conducted at MicroBioTest. Study completion date – 10/29/15. Laboratory Project Identification Number 474-148.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 12735, 22735, and 32735) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.2.09.04.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Sixty (60) glass slide carriers (1inch x 3inches) per product lot per microorganism were inoculated with 0.01 mL of a 48-54 hours old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 31 minutes at 36°C and 21% RH. For each lot of product, separate carriers were sprayed with the product (4 sprays) from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin, to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganisms, sterility, viability, neutralizer effectiveness, and bacteriostasis.

5. MRID 499075-13 "AOAC Germicidal Spray Test Supplemental Vancomycin-Intermediate *Staphylococcus aureus*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-166.

This study was conducted against Vancomycin-Intermediate *Staphylococcus aureus* (VISA), (ATCC 700699). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.2.11.12.15 (copy provided). The product was received ready-to-use. The product lots were

not tested at the LCL and in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36-37°C at 50-52% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Minimum inhibitory concentration of Vancomycin-Intermediate *Staphylococcus aureus* (ATCC 700699) was verified on a representative culture. A single BHIA plate was inoculated in a cross hatch pattern. A Vancomycin Etest® strip was added to the plate in accordance with the manufacturer's directions. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition confirmed antibiotic intermediate of Vancomycin-Intermediate Staphylococcus aureus (ATCC 700699). See table 4, page 10 of the laboratory report.

6. MRID 499075-14 "AOAC Germicidal Spray Test Supplemental Vancomycin-Resistant *Enterococcus faecalis*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-181.

This study was conducted against Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299). Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.2a.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36-37°C at 50-52% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299) to Vancomycin. See table 4, page 10 of the laboratory report

7. MRID 499075-15 "AOAC Germicidal Spray Test – Tuberculocidal" against *Mycobacterium bovis*, BCG" for Weiman 1 Minute Germicidal Solution, by M. Kathryn D. Dormstetter. Study conducted at MICROBIOTEST. Study completion date – 11/04/15. Laboratory Project Identification Number 474-142.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation). Two lots (11595 and 21595) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.3.06.17.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1-inch x 3 inches) per product lot were inoculated with 0.01 mL of a 21±2 days old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 30 minutes at 37°C and 36% RH. For each lot of product, separate carriers were sprayed (8 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 2 minutes at 21°C. Following the exposure period, the remaining liquid was drained from each carrier. The carriers were transferred to individual tubes containing 20 mL of Heat-Inactivated Horse Serum to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. The carriers were transferred to individual tubes containing 20 mL of Modified Proskauer-Beck Medium. From each tube of neutralizer, 2.0 mL were cultured to tubes containing 20 mL of Middlebrook 7H9 Broth and 2.0 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 60 days at 38±1°C. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, and neutralizer effectiveness.

8. MRID 499075-16 "AOAC Germicidal Spray Test Supplemental Carbapenem-Resistant *Escherichia coli*; for Weiman 1 Minute Germicidal Solution; by Kelsey Roach. Study conducted at MicroBioTest. Study completion date – 03/23/16. Laboratory Project Identification Number 474-182.

This study was conducted against Carbapenem-Resistant *Escherichia coli* (ATCC BAA-2471). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.3a.01.05.16 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1inch x 3inches) per product lot were inoculated with 0.01 mL of a 48-54 hours old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 32 minutes at 36°C and 34% RH. For each lot of product, separate carriers were sprayed with the product (4 sprays) from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C and 74% RH. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin, to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganisms, sterility, viability, neutralizer effectiveness, and bacteriostasis.

Note: Antibiotic resistance of Carbapenem-Resistant *Escherichia coli* (ATCC BAA-2471) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 8 mm) confirmed antibiotic resistance of Carbapenem-Resistant *Escherichia coli* (ATCC BAA-2471) to Carbapenem (Imipenem). See Table 4, page 10 of the laboratory report.

9. MRID 499075-17 "AOAC Germicidal Spray Test Supplemental Methicillin-Resistant *Staphylococcus aureus* subsp. aureus Rosenbach" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-167.

This study was conducted against Methicillin-Resistant *Staphylococcus aureus* subsp. *aureus* Rosenbach (ATCC 14154). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.3a.11.12.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* subsp. *aureus* Rosenbach (ATCC 14154) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Methicillin-Resistant *Staphylococcus aureus* subsp. *aureus* Rosenbach (ATCC 14154) to Methicillin (Penicillin). See page 10 of the laboratory report.

10. MRID 499075-18 "AOAC Germicidal Spray Test Supplemental Extended spectrum β-lactamase *Escherichia coli*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-183.

This study was conducted against Extended spectrum β-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196). Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.4a.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each

carrier. The carriers were dried for 32 minutes at 36-37°C at 50-52% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of Extended spectrum β-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were added to the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Extended spectrum β-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196) to Ceftazidime and Penicillin. See page 10 of the laboratory report.

11. MRID 499075-19 "AOAC Germicidal Spray Test Using *Trichophyton mentagrophytes*" Weiman 1 Minute Germicidal Solution; by Candace Robinson. Study conducted at MicroBioTest. Study completion date – 12/02/15. Laboratory Project Identification Number 474-149.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (42735N and 52735N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.4a.09.04.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of conidia suspension from 10-15 days old culture. The carriers were dried for 37 minutes at 36°C and 23-24% RH. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, individual carriers were transferred to Neopeptone Glucose Broth with 7% Polysorbate 80 and 1% Lecithin to neutralize. Tubes containing the neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for up to 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for inoculum count, carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, and fungistasis.

12. MRID 499075-20 "AOAC Germicidal Spray Test Supplemental *Enterococcus faecium*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-168.

This study was conducted against *Enterococcus faecium* (ATCC 51559). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.4a.11.12.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at

3637°C at 50-52% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

Note: Antibiotic resistance of *Enterococcus faecium* (ATCC 51559) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were added to the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of *Enterococcus faecium* (ATCC 51559) to Vancomycin and Gentamicin but protocol indicates the use of Ampicillin and Ciprofloxacin. See pages 10 and 17 of the laboratory report.

13. MRID 499075-21 "AOAC Germicidal Spray Test Supplemental *Acinetobacter baumannii*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-169.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.5.11.12.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, and bacteriostasis.

14. MRID 499075-22 "Virucidal Hard-Surface Efficacy Test - Duck Hepatitis B Virus (Surrogate for Human Hepatitis B Virus)" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 03/31/16. Laboratory Project Identification Number 474-185.

This study was conducted against Duck Hepatitis B virus (DHBV), Strain: Grimaud (obtained from HepadnaVirus Testing, Inc.), using primary duck hepatocytes cells (obtained from ducklings at Metzer Farms) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested according to a MICROBIOTEST protocol no. 474.6.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL but in the presence of at least 5% organic soil load. The stock virus culture contained 100% duck serum. Films of virus were prepared by

spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 21°C and 24.7 - 30.4% RH. Two replicates were tested per lot. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 28 seconds at 21°C. Following exposure, the plates were neutralized with 2.0 mL of L-15 complete with 10% Fetal Bovine Serum (FBS), 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were diluted serially in L-15 Complete and assayed. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with the dilutions. The cultures were incubated for 20-30 hours at 36±2°C in 5±1% CO_2 for viral adsorption. Following adsorption, the cultures were refed. The cultures were returned to incubation for 10-14 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the infectious virus was assayed by an immunofluorescence assay according to MicroBioTest SOP M1006.Vl.013 (current version). Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

15. MRID 499075-23 "AOAC Germicidal Spray Test Supplemental Multi-Drug Resistant *Acinetobacter baumannii*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-170.

This study was conducted against Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.6.11.12.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, and bacteriostasis.

Note: Antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were added to the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Multi-Drug Resistant *Acinetobacter baumannii* (ATCC BAA-1605) to Ceftazidime and Gentamicin. See Table 4, pages 10 of the laboratory report.

16. MRID 499075-24 "Virucidal Hard-Surface Efficacy Test - Bovine Viral Diarrhea Virus (BVDV), Strain: NADL (Surrogate for Human Hepatitis B Virus)" for Weiman 1

Minute Germicidal Solution by Cameron Wilde. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-186.

This study was conducted against Bovine Viral Diarrhea Virus (BVDV), Strain: NADL (obtained from American Bioresearch Laboratories), using MDBK cells (ATCC CCL-22) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.7.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 21°C and 23.4-24.8% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 28 seconds at 21°C. Following exposure, the plates were neutralized with 2.0 mL of Minimum Essential Medium (MEM) with 10% horse serum, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 2% horse serum. MDBK cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

17. MRID 499075-25 "Virucidal Hard-Surface Efficacy Test – Herpes Simplex Virus Type 2" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-187.

This study was conducted against Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734), using Vero cells (ATCC CCL-81) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.8.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20°C and 24.8-25.0% RH. One replicate was tested per lot. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, the plates were neutralized with 2.0 mL of Minimum Essential Medium (MEM) with 10% horse serum, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 2% Newborn Calf Serum (NCS). Vero cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 5-8 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50%

tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

18. MRID 499075-26 "AOAC Germicidal Spray Test Supplemental *Bordetella pertussis*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 03/23/16. Laboratory Project Identification Number 474-184.

This study was conducted against *Bordetella pertussis* (ATCC BAA-589). Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.5a.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 35 minutes at 36°C at 31% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Bordet Gengou Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, bacteriostasis, and antibiotic resistance.

19. MRID 499075-27 "AOAC Germicidal Spray Test Supplemental *Pseudomonas aeruginosa*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-171.

This study was conducted against *Pseudomonas aeruginosa* (ATCC BAA-2108). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.8a.11.12.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, and bacteriostasis.

Note: Antibiotic resistance of *Pseudomonas aeruginosa* (ATCC BAA-2108) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were added to the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented.

The measured zone of inhibition (i.e., 2 mm) confirmed antibiotic resistance of *Pseudomonas aeruginosa* (ATCC BAA-2108) to Imipenem. See Table 4, page 10 of the laboratory report.

20. MRID 499075-28 "Virucidal Hard-Surface Efficacy Test – Herpes Simplex Virus Type 1" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-188.

This study was conducted against Herpes Simplex Virus Type 1, Strain: F(1) (ATCC VR-733), using Vero cells (ATCC CCL-81) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.8.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20°C and 25.6-25.9% RH. One replicate was tested per lot. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in MEM with 2% FBS. Vero cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 5-8 days at 34±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

21. MRID 499075-29 "AOAC Germicidal Spray Test Supplemental *Klebsiella pneumoniae*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-172.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (33275N and 43275N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.9.11.12.15 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL and not in the presence of a 5% organic soil load. Ten sterile glass carriers (1-inch x 1-inch) per product lot per microorganism were inoculated with 10.0 µL of a 48-54 hours old suspension of test organism. The inoculum was spread to within 1/8 inch of the edges of each carrier. The carriers were dried for 32 minutes at 36°C at 42-44% Relative Humidity. Each carrier was transferred to a plastic Petri dish and was sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20-21°C. Following exposure, each carrier was placed into a sterile vessel containing 20 mL of Letheen Broth with 1% Lecithin and 7% Polysorbate 80. All subculture tubes containing the carriers were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganism, sterility, viability, neutralizer effectiveness, and bacteriostasis.

22. MRID 499075-30 "Virucidal Hard-Surface Efficacy Test - Human Immunodeficiency Virus Type 1, Strain: IIIB (B)" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-189.

This study was conducted against Human Immunodeficiency Virus Type 1, Strain: IIIB (B) (obtained from ZeptoMetrix), using C8166 cells (obtained from University of Pennsylvania)) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.10.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20°C and 24.6-27.9% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 28 seconds at 20°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 2% FBS. C8166 cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 9-12 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

23. MRID 499075-31 "AOAC Germicidal Spray Test Supplemental Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1)" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-173.

This study was conducted against Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.10.11.12.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1inch x 3inches) per product lot were inoculated with 0.01 mL of a 48-54 hours old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 32 minutes at 36-37°C and 50-52% RH. For each lot of product, separate carriers were sprayed with the product (4 sprays) from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C and 28-31% RH. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin, to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 37±2°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for

carrier counts, confirmation of the challenge microorganisms, sterility, viability, neutralizer effectiveness, and bacteriostasis.

Note: Antibiotic resistance of Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, an antibiotic disk was added to the center of the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470) to Carbapenem (Imipenem). See Table 4, page 10 of the laboratory report.

24. MRID 499075-32 "Virucidal Hard-Surface Efficacy Test - Influenza A Virus (H1N1)" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-190.

This study was conducted against Influenza A Virus (H1N1), Strain: A/PR/8/34 (obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.11.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 21°C and 31.1-33.7% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 21°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 3.0 µg/ml Trypsin. MDCK cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

25. MRID 499075-33 "AOAC Germicidal Spray Test Supplemental - *Enterobacter aerogenes*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-174.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.11.11.12.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1inch x 3inches) per product lot were inoculated with 0.01 mL of a 48-54 hours old suspension of test organism. Inoculum was transferred onto a

one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 32 minutes at 36-37°C and 50-52% RH. For each lot of product, separate carriers were sprayed with the product (4 sprays) from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C and 28-31% RH. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin, to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganisms, sterility, viability, neutralizer effectiveness, and bacteriostasis.

26. MRID 499075-34 "Virucidal Hard-Surface Efficacy Test - Influenza A Virus (H3N2)" for Weiman 1 Minute Germicidal Solution by Zheng Chen. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-191.

This study was conducted against Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68 (obtained from Charles River Laboratories), using MDCK cells (ATCC CCL-34) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.12.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 21°C and 25.8-27.1% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 21°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 3.0 µg/ml Trypsin. MDCK cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 4-6 days at 36±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

27. MRID 499075-35 "AOAC Germicidal Spray Test Supplemental - *Enterobacter cloacae*" for Weiman 1 Minute Germicidal Solution; by Tatiana Ballreich. Study conducted at MicroBioTest. Study completion date – 02/29/16. Laboratory Project Identification Number 474-175.

This study was conducted against *Enterobacter cloacae* (ATCC BAA-2341). Two lots (13275L and 23275L) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.12a.11.12.15 (copy provided). The product was received ready-to-use. The product lots were tested at the LCL but not in the presence of a 5% organic soil load. Ten (10) glass slide carriers (1inch x 3inches) per product lot were inoculated

with 0.01 mL of a 48-54 hours old suspension of test organism. Inoculum was transferred onto a one square inch area of each carrier and immediately spread uniformly over the entire area. The carriers were dried for 32 minutes at 36-37°C and 50-52% RH. For each lot of product, separate carriers were sprayed with the product (4 sprays) from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C and 28-31% RH. Following the exposure period, the remaining liquid was drained from each carrier. Following the exposure period, individual carriers were transferred to tubes containing Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin, to neutralize. The tubes containing neutralizer were shaken thoroughly after addition of the carriers. All subcultures were incubated for 48±2 hours at 36±1°C. Following incubation, the subcultures and streaks were examined for the presence or absence of visible growth. Controls included those for carrier counts, confirmation of the challenge microorganisms, sterility, viability, neutralizer effectiveness, and bacteriostasis.

Note: Antibiotic resistance of *Enterobacter cloacae* (ATCC BAA-2341) was verified on a representative culture. An individual Mueller Hinton Agar was streaked with the prepared culture in a crosshatch pattern. After crosshatching, antibiotic disks were added to the plate. The plate was incubated and, following incubation, the zone of inhibition was measured and documented. The measured zone of inhibition (i.e., 0 mm) confirmed antibiotic resistance of *Enterobacter cloacae* (ATCC BAA-2341) to Imipenem. See Table 4, page 10 of the laboratory report.

28. MRID 499075-36 "Virucidal Hard-Surface Efficacy Test – Human Coronavirus" for Weiman 1 Minute Germicidal Solution by Cameron Wilde. Study conducted at MicroBioTest. Study completion date – 04/01/16. Laboratory Project Identification Number 474-192.

This study was conducted against Human Coronavirus, Strain: 229E (ATCC VR-740), using MRC-5 cells (ATCC CCL-171) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.13.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20°C and 28.4-29.7% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 2% FBS. MRC-5 cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 5-7 days at 33±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

29. MRID 499075-37 "Virucidal Hard-Surface Efficacy Test – Rotavirus" for Weiman 1 Minute Germicidal Solution by Cameron Wilde. Study conducted at MicroBioTest.

Study completion date – 04/01/16. Laboratory Project Identification Number 474-192.

This study was conducted against Rotavirus, Strain: 229WA (TC adapted) (ATCC VR-2018), using MRC-5 cells (ATCC CCL-171) as the host system. Two lots (10046N and 20016N) of the product, Weiman 1 Minute Germicidal Solution (Opti-Cide Max), were tested using MicroBioTest Protocol No. 474.13.01.05.16 (copy provided). The product was received ready-to-use. The product lots were not tested at the LCL. The stock virus culture contained 5% organic soil load. Films of virus were prepared by spreading 0.4 mL of virus inoculum over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 30 minutes at 20°C and 28.4-29.7% RH. Two replicates were tested. Dried virus films were separately sprayed (4 pumps) with the product from a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 58 seconds at 20°C. Following exposure, the plates were neutralized with 2.0 mL of MEM with 10% FBS, 0.5% Polysorbate 80, and 0.5% Lecithin. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant-neutralizer mixtures were passed immediately through individual Sephacryl columns, and diluted serially in Minimal Essential Medium with 2% FBS. MRC-5 cells in multi-well culture dishes were inoculated with the dilutions. The cultures were incubated for 5-7 days at 33±2°C in 5±1% CO_2. The cultures were re-fed, as necessary. Following incubation, the cultures were examined microscopically for the presence of infectious virus. Controls included those for cell viability/sterility, virus stock titer, column titer count, plate recovery count, cytotoxicity, and neutralizer effectiveness/viral interference. The 50% tissue culture infectious dose per mL ($TCID_{50}$/mL) was determined using the method of Spearman Karber.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Counts (CFU/ carrier)
		Lot No. 12735	Lot No. 22735	Lot No. 32735	
58 Seconds Exposure Time					
499075-12	*Staphylococcus aureus*	1/60	0/60	0/60	1.86×10^6
	Salmonella enterica	0/60	1/60	0/60	4.6×10^5
	Pseudomonas aeruginosa	1/60	1/60	0/60	1.185×10^6
		Lot No. 33275N	**Lot No. 43275N**		
499075-09	Methicillin-Resistant *Staphylococcus aureus*	0/10	0/10	---	2.8×10^6
499075-13	Vancomycin-Intermediate *Staphylococcus aureus*	0/10	0/10	---	4.4×10^5
499075-17	Methicillin-Resistant *Staphylococcus aureus* subsp. aureus Rosenbach	0/10	0/10	---	1.5×10^6
499075-20	*Enterococcus faecium*	0/10	0/10	---	2.7×10^5
499075-21	*Acinetobacter baumannii*	0/10	0/10	---	1.1×10^5
499075-29	*Klebsiella pneumoniae*	0/10	0/10	---	8.9×10^4

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Counts (CFU/ carrier)
		Lot No. 12735	Lot No. 22735	Lot No. 32735	
		Lot No. 10046N	Lot No. 20016N		
499075-10	Methicillin-Resistant *Staphylococcus epidermidis*	0/10	0/10	---	2.5×10^5
499075-14	Vancomycin-Resistant *Enterococcus faecalis*	0/10	0/10	---	8.2×10^5
499075-18	Extended spectrum β-lactamase *Escherichia coli*	0/10	0/10	---	8.4×10^5
499075-26	*Bordetella pertussis*	0/10	0/10	---	2.7×10^5
		Lot No. 13275L	Lot No. 23275L		
499075-16	Carbapenem-Resistant *Escherichia coli*	0/10	0/10	---	1.5×10^6
499075-23	Multi-Drug Resistant *Acinetobacter baumannii*	0/10	0/10	---	1.9×10^6
499075-27	*Pseudomonas aeruginosa*	0/10	0/10	---	1.9×10^6
499075-31	Carbapenem-Resistant *Klebsiella pneumoniae*	0/10	0/10	---	1.9×10^6
499075-33	*Enterobacter aerogenes*	0/10	0/10	---	1.2×10^6
499075-35	*Enterobacter cloacae*	0/10	0/10	---	2.4×10^5
		Lot No. 42735N	Lot No. 52735N		
499075-19	*Trichophyton mentagrophytes*	0/10	0/10	---	2.5×10^4

MRID Number	Organism	Media	No. Exhibiting Growth/ Total No. Tested	
			Lot No. 11595 90 Days	Lot No. 21595 90 Days
1-Minute 58 Seconds Exposure Time				
499075-15	*Mycobacterium bovis* BCG Carrier Population: 4.0×10^4 CFU/carrier	Modified Proskauer-Beck Medium	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10
		Kirchner's Medium	0/10	0/10

MRID Number	Organism	Description	Results		Dried Virus Control ($TCID_{50}$/Carrier)
			Lot No. 12735	Lot No. 22735	
58 Seconds Exposure Time					
499075-11	Feline Calicivirus (FCV), Strain: F9 (ATCC VR-782)	10^{-3} dilution	Cytotoxic	Cytotoxic	$10^{7.53}$
		10^{-4} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{4.40}$	$\leq 10^{4.40}$	
		Log Reduction	≥3.13	≥3.13	

			Lot No. 10046N	**Lot No. 20016N**	
499075-25	Herpes Simplex Virus Type 2, Strain: G	10^{-2} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.95}$
		$TCID_{50}$/carrier	$\leq 10^{2.70}$	$\leq 10^{2.70}$	
		Log Reduction	≥3.25	≥3.25	
499975-28	Herpes Simplex Virus Type 1, Strain: F(1)	10^{-2} dilution	Cytotoxic	Cytotoxic	$10^{6.88}$
		10^{-3} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.75}$	$\leq 10^{3.75}$	
		Log Reduction	≥3.13	≥3.13	
499075-32	Influenza A Virus (H1N1), Strain: A/PR/8/34	10^{-2} – 10^{-3} dilutions	Cytotoxic	Cytotoxic	$10^{6.95}$
		10^{-4} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.45}$	$\leq 10^{3.45}$	
		Log Reduction	≥3.50	≥3.50	
499075-34	Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68	10^{-2} – 10^{-3} dilutions	Cytotoxic	Cytotoxic	$10^{6.95}$
		10^{-4} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.45}$	$\leq 10^{3.45}$	
		Log Reduction	≥3.50	≥3.50	
499075-36	Human Coronavirus, Strain: 229E	10^{-2} – 10^{-3} dilutions	Cytotoxic	Cytotoxic	$10^{6.40}$
		10^{-4} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.40}$	$\leq 10^{3.40}$	
		Log Reduction	≥3.00	≥3.00	
499075-37	Rotavirus, Strain: 229WA (TC adapted)	10^{-2} dilution	Cytotoxic	Cytotoxic	$10^{6.90}$
		10^{-3} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{2.40}$	$\leq 10^{2.40}$	
		Log Reduction	≥4.50	≥4.50	
28 Seconds Exposure Time					
			Lot No. 12735	**Lot No. 22735**	
499075-22	Duck Hepatitis B Virus	10^{-2} dilution	Cytotoxic	Cytotoxic	$10^{5.54}$
		10^{-3} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{2.40}$	$\leq 10^{2.40}$	
		Log Reduction	≥3.14	≥3.14	

			Lot No. 10046N	Lot No. 20016N	
499075-24	Bovine Viral Diarrhea Virus (as a Surrogate Virus for Human Hepatitis C Virus)	10^{-2} dilution	Cytotoxic	Cytotoxic	$10^{6.83}$
		10^{-3} - 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.70}$	$\leq 10^{3.70}$	
		Log Reduction	≥3.13	≥3.13	
499075-30	Human Immunodeficiency Virus Type 1, Strain: IIIB (B)	10^{-2} dilution	Cytotoxic	Cytotoxic	$10^{6.83}$
		10^{-3} - 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/carrier	$\leq 10^{3.70}$	$\leq 10^{3.70}$	
		Log Reduction	≥3.13	≥3.13	

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Opti-Cide Max, as a disinfectant with bactericidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 58-second contact time:

Staphylococcus aureus (ATCC 6538) MRID 499075-12
Salmonella enterica (ATCC 10708) MRID 499075-12
Pseudomonas aeruginosa (ATCC 15442) MRID 499075-12
Methicillin-Resistant Staphylococcus aureus (MRSA) (ATCC 33592) MRID 499075-09
Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625) MRID 499075-10
Vancomycin-Intermediate *Staphylococcus aureus* (VISA), (ATCC 700699) MRID 499075-13
Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299) MRID 499075-14
Carbapenem-Resistant *Escherichia coli* (ATCC BAA-2471) MRID 499075-16
Methicillin-Resistant *Staphylococcus aureus* subsp. *aureus* Rosenbach (ATCC 14154) MRID 499075-17
Extended spectrum β-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196) MRID 499075-18
Enterococcus faecium (ATCC 51559) MRID 499075-20
Acinetobacter baumannii (ATCC 19606) MRID 499075-21
Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605) - (Resistant to Ceftazidime and Gentamicin) MRID 499075-23
Bordetella pertussis (ATCC BAA-589) MRID 499075-26
Pseudomonas aeruginosa (ATCC BAA-2108) MRID 499075-27
Klebsiella pneumoniae (ATCC 4352) MRID 499075-29
Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470) MRID 499075-31
Enterobacter aerogenes (ATCC 13048) MRID 499075-33
Enterobacter cloacae (ATCC BAA-2341) MRID 499075-35

2. The submitted confirmatory efficacy data **support** the use of the product, Opti-Cide Max, as a disinfectant with virucidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 58-second contact time:

Feline Calicivirus (FCV), Strain: F9 (ATCC VR-782) MRID 499075-11
Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734) MRID 499075-25

Herpes Simplex Virus Type 1, Strain: F(1) (ATCC VR-733)	MRID 499075-28
Influenza A Virus (H1N1), Strain: A/PR/8/34	MRID 499075-32
Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68	MRID 499075-34
Human Coronavirus, Strain: 229E (ATCC VR-740)	MRID 499075-36
Rotavirus, Strain: 229WA (TC adapted) (ATCC VR-2018)	MRID 499075-37

3. The submitted confirmatory efficacy data **support** the use of the product, Opti-Cide Max, as a disinfectant with virucidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 28-second contact time:

Duck Hepatitis B virus (DHBV), Strain: Grimaud	MRID 499075-22
Bovine Viral Diarrhea Virus (BVDV), Strain: NADL	MRID 499075-24
Human Immunodeficiency Virus Type 1, Strain: IIIB (B)	MRID 499075-30

4. The submitted efficacy data (MRID 499075-15) **support** the use of the product, Opti-Cide Max, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on pre-cleaned, hard, non-porous surfaces for a 1 minute 58 seconds contact time.

5. The submitted confirmatory efficacy data (MRID 499075-19) **do not support** the use of the product, Opti-Cide Max, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* (ATCC 9533) on pre-cleaned, hard, non-porous surfaces for a 58-second contact time. **Product lots tested were not at the LCL.**

VII. LABEL

1. The proposed label claims that the product, Opti-Cide Max, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 1-minute contact time:

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)
Pseudomonas aeruginosa (ATCC 15442)
Vancomycin-Intermediate *Staphylococcus aureus* (VISA), (ATCC 700699)
Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51299)
Carbapenem-Resistant *Escherichia coli* (ATCC BAA-2471)
Methicillin-Resistant Staphylococcus aureus (MRSA) (ATCC 33592)
Methicillin-Resistant *Staphylococcus epidermidis* (MRSE) (ATCC 51625)
Methicillin-Resistant *Staphylococcus aureus* subsp. *aureus* Rosenbach (ATCC 14154)
Extended-Spectrum β-lactamase (ESBL) *Escherichia coli* (ATCC BAA-196)
Enterococcus faecium (ATCC 51559)
Acinetobacter baumannii (ATCC 19606)
Multi-Drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605) (Resistant to Ceftazidime and Gentamicin)
Bordetella pertussis (ATCC BAA-589)
Pseudomonas aeruginosa (ATCC BAA-2108)
Klebsiella pneumoniae (ATCC 4352)
Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470)
Enterobacter aerogenes (ATCC 13048)
Enterobacter cloacae (ATCC BAA-2341)
Norovirus (Norwalk Virus) [Feline Calicivirus (FCV), Strain: F9 (ATCC VR-782)]

Herpes Simplex Virus Type 2, Strain: G (ATCC VR-734)
Herpes Simplex Virus Type 1, Strain: F(1) (ATCC VR-733)
Influenza A Virus (H1N1), Strain: A/PR/8/34
Influenza A Virus (H3N2), Strain: A/Hong Kong/8/68
Human Coronavirus, Strain: 229E (ATCC VR-740)
Rotavirus, Strain: 229WA (TC adapted) (ATCC VR-2018)

These claims are acceptable as they are supported by the submitted data. **Registrant must qualify "Multi-Drug" and list the 2 drugs, Ceftazidime and Gentamicin.**

2. The proposed label claims that the product, Opti-Cide Max, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 30-second contact time:

Hepatitis B Virus (HBV) [Duck Hepatitis B virus (DHBV), Strain: Grimaud]
Hepatitis C Virus (HCV) [Bovine Viral Diarrhea Virus (BVDV), Strain: NADL]
Human Immunodeficiency Virus Type 1, Strain: IIIB (B)

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the product, Opti-Cide Max, is an effective disinfectant with tuberculocidal activity against *Mycobacterium bovis BCG*, on pre-cleaned, hard, non-porous surfaces for a 2-minute contact time **are acceptable, as they are supported by the submitted data.**

4. The proposed label claims that the product, Opti-Cide Max, is an effective disinfectant with fungicidal activity against *Trichophyton mentagrophytes* (ATCC 9533) on pre-cleaned, hard, non-porous surfaces for a 60-second contact time **are not acceptable as they are not supported by the submitted data**. **Registrant must remove fungicidal claims**.

5. The following revision must be made to the proposed label:

- On page 1 of the label, list the correct ATCC no. 51299 for VRE; list *Acinetobacter baumannii* (ATCC 19606) as a Gram-Negative microorganism; qualify MDR and list the drugs.
- On page 2 of the label, remove "*Trichophyton mentagrophytes* [(ringworm)] [ATCC 9533], "Norwalk Like Virus", and the second "Carbapenem-Resistant *Klebsiella pneumoniae* (NDM-1) (ATCC BAA-2470)" from the list of "Gram-Negative Bacteria"; list "Influenza A Virus (H1N1) as an "Enveloped Virus".
- Remove all "fungus", "fungi", fungicide", "fungicidal", "fungistatic", "mildewstatic", "mildewstat", "mold and mildew" claims on the label.
- Granite, stone and vinyl are porous unless sealed, thus the label should identify these surfaces as "sealed" if they are indicated for disinfection. Ropes and halters are porous surfaces.
- Remove the claim (page 8) "microfiber [approved] [compatible]."
- Remove all "decontaminant", "decontaminating", "decontaminate", "decontamination" claims on the label.
- Remove all "Quick", Quickly", "Easy", "Fast Kill Time", "Fast acting", and "Fast" claims. Only contact times of 30 seconds or less are consider by the Agency for those claims.
- Remove terms "optimum", "has never been faster", "easier", "more convenient" and "particularly effective" from the label as they imply comparison.

- All disinfection directions for use should specify application by spray.
- Under “vehicle disinfection” application with high pressure water should be removed or revised to indicate a standard spray application.
- All label references to reduction or control of HAI’s and/or Hospital Acquired Infections should be removed.
- Remove the page 10 claims (2 locations) “protects patients and staff...”
- All label references to cross contamination should be qualified with the statement “…on treated surfaces” or “…from treated surfaces.”
- Under the “Surfaces” section (page 13) the first sentence should be revised to read “This product can be used on the hard, non-porous surfaces of the following items”